

Minutes of Conference Call to Discuss Data Management

October 10, 2002

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Participants

Covance

David Coggin

Mary Larson

Jill Schultz

MDS

Tony Cavaliere

Bob Lynch

Kimberly Prchal

Philip Morris

Bettie Nelson

Jan Oey

Etrials

Jodi Pickering

Dana Winsted

The following items were reviewed/discussed:

Transfer of eCRFs and Topography Data

Data will be sent as SAS data sets by etrials on a monthly basis via email (password protected). etrials will only send CRFs that have been monitored or locked. Data are to be sent the first Monday of each month. Send email to Steven Zweig (steven.zweig@mdsps.com) and Bob Lynch (bob.lynn@mdsps.com). Steve will be the main contact. Contact information is as follows:

Steven Zweig

Mngr. Biostatistics

MDS Pharma Services Inc.

2200 Renaissance Blvd.

King of Prussia, PA 19406

TEL: 610-239-7900 ext.493

FAX: 610-275-6246

This list of edit checks will be sent to Steven Zweig for MDS to review. Edit checks need to be put into place as soon as possible. Mary Larson asked that she be notified prior to the edit checks being released so that she can notify the sites. Dana Winsted indicated that a message board can be used to notify the sites when edit checks will be put in place.

ACTION: D. Winsted/S. Zweig

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Transfer of eCRFs and Topography Data (Continued)

Topography data will also be sent monthly (first Monday of the month) as .txt files to Steven Zweig via email. Following review by MDS, the frequency of sending the files may change. Topography data will be cleaned by MDS in consultation with Philip Morris.

ACTION: S. Zweig to contact D. Winsted if frequency of transfer of topography data will change.

Transfer of Questionnaire Data

Questionnaire data will be sent monthly (same as above). David Coggin indicated that the CRU will resolve issues such as questionable marks, miss scans, etc., but that there is really not data cleaning. The questionnaires are not monitored as there is no source data to check. The sites will make sure skip patterns are followed and that circles are filled in completely.

Transfer of Bioanalytical and CCLS Data

Bioanalytical (Harrogate) and CCLS data will be sent monthly to MDS as a SAS data sets by the Harrogate, Indianapolis, and Madison CRU offices, respectively. MDS will define format for CCLS and bioanalytical data. This needs to be done as soon as possible as data can not be sent until format is defined and database is set up. Bioanalytical data will be QA'd prior to sending to MDS.

ACTION: MDS to define format for bioanalytical and CCLS data.

MDS Contract with etrials

Jodi Pickering indicated that a confidentiality agreement and task order needs to be sent up MDS.

ACTION: S. Zweig to provide Jodi with contact information for contract person at MDS.

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